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The Effect of a Bio-Behavioral Intervention on the Release of Cytokines

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HU0-001-09-TS14

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6. AUTHOR(S)
Burge, Donna, LT, USN, NC, PhD, RN

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N09-C07

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N/A

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Henry M. Jackson Foundation
1401 Rockville Pike, Suite 600, Rockville, MD 20852

8. PERFORMING ORGANIZATION REPORT NUMBER
N/A

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
TriService Nursing Research Program, 4301 Jones Bridge RD
Bethesda, MD 20814

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TSNRP

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
N09-C07

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Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES
N/A

14. ABSTRACT

Purpose: The purpose of this study was examining effects of guided imagery on the release of pro-inflammatory cytokines and neuropeptides as well as anxiety and pain perioperatively. **Design:** Study design was a two-group randomized controlled trial study. **Methods:** Participants were randomly assigned into two groups. The experimental group listened to guided imagery recordings immediately before and during the surgical procedure. The control group underwent usual perioperative care. Participants were randomly placed in treatment or control groups. Treatment group participants listened to an audio guided imagery intervention 30 minutes prior to and continuing through the surgery. Control group participants received usual perioperative care. All participants completed the anxiety and pain scales in the preoperative holding area, immediately postoperatively, and at scheduled intervals during the initial 48 hours following surgery. Blood samples were drawn pre-, intra- (30 minutes after skin incision), and postoperatively (30 minutes after transfer to the post anesthesia care unit) to monitor IL-6, IL-8, and Substance P levels. Anxiety scale, pain scale, cytokines IL6 and IL8, and Substance P values were analyzed for changes over time and between study groups. **Sample:** Sample consisted of sixty-eight adult females (ASA Classes I-III) undergoing laparoscopic gynecological procedures under general anesthesia. **Analysis:** A linear random coefficient regression model was utilized. It is a hierarchical mixed effects model permitting estimation of subject and population level change over time in the presence of both autocorrelation, as within-subject repeated measures and missing data. **Findings:** Higher preoperative anxiety levels appeared to be associated with increased IL-6 and IL-8 levels over time in both groups. Both groups reported higher levels of pain postoperatively. **Implications for Military Nursing:** Pain impacts operational readiness and wartime functionality. This investigation provides data on a practical intervention to decrease pain medication needs, hospital stays and earlier return of service members to work.

15. SUBJECT TERMS Pain Management, Cytokine, Behavioral Intervention					
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TriService Nursing Research Program Final Report Cover Page

Sponsoring Institution Address of Sponsoring Institution	TriService Nursing Research Program 4301 Jones Bridge Road Bethesda MD 20814
USU Grant Number	HU0-001-09-TS14
USU Project Number	N09-C07
Title of Research Study or Evidence-Based Practice (EBP) Project	"The Effect of a Bio-Behavioral Intervention on the Release of Cytokines"
Period of Award	1 September 2009 to 30 June 2012
Applicant Organization	Henry M. Jackson Foundation for the Advancement of Military Medicine
Address of Applicant Organization	1401 Rockville Pike, Suite 600 Rockville, MD 20852

Principal Investigator (PI) Military Contact Information

Duty Title	Donna M. Burge LT, USN, NC, PhD, BC-APRN, CNS
Telephone	[redacted]
Mobile Telephone	[redacted]
E-mail Address	[redacted]

PI Civilian Work Contact Information

Duty Title	[redacted]
Employer	[redacted]
Address	[redacted]
Mobile Telephone	[redacted]
E-mail Address	[redacted]

PI Home Contact Information

Address	[redacted]
Telephone	[redacted]
Mobile Telephone	[redacted]
E-mail Address	[redacted]

Signatures

PI Signature _____ Date _____

Mentor Signature _____ Date _____

Table of Contents

Abstract

Purpose
The purpose of this study was examining effects of guided imagery on the release of pro-inflammatory cytokines and neuropeptides as well as anxiety and pain perioperatively**.**

Design
Study design was a two-group randomized controlled trial study.

Methods
Participants were randomly assigned into two groups. The experimental group listened to guided imagery recordings immediately before and during the surgical procedure. The control group underwent usual perioperative care. Participants were randomly placed in treatment or control groups. Treatment group participants listened to an audio guided imagery intervention 30 minutes prior to and continuing through the surgery. Control group participants received usual perioperative care. All participants completed the anxiety and pain scales in the preoperative holding area, immediately postoperatively, and at scheduled intervals during the initial 48 hours following surgery. Blood samples were drawn pre-, intra- (30 minutes after skin incision), and postoperatively (30 minutes after transfer to the post anesthesia care unit) to monitor IL-6, IL-8, and Substance P levels. Anxiety scale, pain scale, cytokines IL6 and IL8, and Substance P values were analyzed for changes over time and between study groups.

Sample
Sample consisted of sixty-eight adult females (ASA Classes I-III) undergoing laparoscopic gynecological procedures under general anesthesia.

Analysis
A linear random coefficient regression model was utilized. It is a hierarchical mixed effects model permitting estimation of subject and population level change over time in the presence of both autocorrelation, as within-subject repeated measures and missing data.

Findings
Higher preoperative anxiety levels appeared to be associated with increased IL-6 and IL-8 levels over time in both groups. Both groups reported higher levels of pain postoperatively.

Implications for Military Nursing
Pain impacts operational readiness and wartime functionality. This investigation provides data on a practical intervention to decrease pain medication needs, hospital stays and earlier return of service members to work.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☒ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Secondary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Progress Towards Achievement of Specific Aims of the Study or Project

Findings related to each specific aim, research or study questions, and/or hypothesis

Hypothesis I

Preoperative application of guided imagery will reduce perioperative production of the pro-inflammatory cytokines and Substance P.

Specific Aims

1. Compare the plasma levels of pro-inflammatory cytokines and Substance P perioperatively between subjects exposed to auditory guided imagery with those subjects having no intervention.

Hypothesis II

Preoperative application of guided imagery will reduce preoperative anxiety and severity of postoperative pain.

Specific Aims

1. Determine preoperative anxiety and pain levels in subjects preoperatively exposed to auditory guided imagery versus no intervention.
2. Determine postoperative pain severity in subjects exposed to pre and intraoperative auditory guided imagery versus no intervention.
3. Correlate changes in preoperative anxiety level, postoperative pain severity, and pro-inflammatory cytokines and Substance P.

Our hypothesis suggested that patients receiving the guided imagery intervention would have a decrease in both pain and anxiety. Pain was measured utilizing the Visual Analog Scale. Both Interleukin-6 and Interleukin-8 (IL-6 and IL-8) demonstrated a relationship with preoperative anxiety scores (B 0.003; SE 0.001; P=0.003; and B 0.002; SE 0.0005; P=0.0002). Higher preoperative anxiety levels as measured by the Amsterdam Preoperative Anxiety Information Scale (APAIS) were associated with increased IL-6 and IL-8 levels over time in both experimental and control groups. All participants reported pain postoperatively. The results revealed a statistically significant difference in only one variable. In the treatment group, an unexpected increase in IL6 presented with a p value of 0.02. The data showed that IL6 levels increased at a greater rate in the treatment group than in the control group. When evaluating IL8 levels there were no statistically significant changes in either the treatment group or the control group. Collected data related to VAS and APAIS scales demonstrated an absence of significant difference in either the VAS or APAIS scales for the control group or the treatment. Therefore, in conclusion, exposure to guided imagery was associated with a more rapid rise in IL6 levels during the progression of anesthesia and had no effect on the plasma levels of IL8, VAS or APAIS scales over time. Deviance tests comparing models A and B random coefficient regression analyses of substance P levels over time demonstrated that the addition of treatment and the treatment by time interaction resulted in a significant decrease in model fit ($\chi 22 = 10.9$; $p < 0.01$), leading to the rejection of model B and the conclusion that treatment group and the treatment-by-time interaction are not significant predictors of IL8 levels over time. Model parameters demonstrated a nonsignificant linear trend for time ($F1,184 = .121$; $p = 0.728$) and a

nonsignificant effect of exposure to anesthesia ($F_{1,184} = 2.39$, $p = 0.124$). Therefore, treatment had no effect on Substance P levels over time.

Relationship of current findings to previous findings

Past investigations suggested guided imagery administered prior to a surgical procedure could diminish preoperative anxiety and reduce postoperative surgical pain, opioid utilization and overall length of postoperative hospital stay.[1, 2-5] Our intent was to further exam the perioperative production of proinflammatory cytokines IL6 and IL8 and the neuropeptide Substance P in association with the use of guided imagery pre- and intraoperatively. With the knowledge of IL6 and IL8 being proinflammatory mediators and encouraging heightened pain as well as Substance P elevating in response to painful stimuli, we expected guided imagery would cause a reduction in these levels. Contrary to our expectations, there were no significant changes in IL8 or Substance P and a modest increase in IL6 in both the control group and the treatment group.

IL-6 is an inflammatory and nociceptive biochemical mediator released in response to pain following tissue injury and has been known to contribute in the control of leukocyte migration and recruitment during acute inflammation.[5] IL-6 induces systemic symptoms by initiating an acute phase response, differentiation of B-cells and macrophages, and T-cell activation contributing to the inflammatory immune response. In several studies, elevated IL-6 production has been observed among surgical patients and patients subjected to external application of pain without break in skin tissue.[13] Comparison of inflammatory indices between open nephrolithotomy and percutaneous nephrolithomy (PCNL) procedures demonstrated a significant rise in IL-6 24 hours postoperatively in groups.[13]

Multiple studies demonstrated hyperalgesic effects of interleukin-8 (IL-8). IL-8 is a pro-inflammatory cytokine produced by macrophages and endothelial cells. IL-8 mediates the neurotransmission of pain associated with the inflammatory response to tissue injury. Eighteen patients receiving analgesia prior to the initiation of the surgical procedure displayed less pain and decreased IL-8 levels postoperatively. Rittner, Machelska, and Stein (2005) witnessed the hyperalgesia effects of IL- injected subcutaneously into the hind paw of rats and mice.[7] Kuo et al. (2006) discovered that subjects who received epidural analgesia or intravenous lidocaine demonstrated less increase in levels of pro-inflammatory cytokines to include IL-8 and lesser severity of postoperative pain than subjects who received only intravenous opiates.[8]

The sensory function of substance P is thought to be related to the transmission of pain information into the central nervous system. Substance P coexists with the excitatory neurotransmitter glutamate in primary afferents that respond to painful stimulation. Substance P has been associated with the regulation of pain and nociception.[9] Substance P is involved in nociception, transmitting information about tissue damage from peripheral receptors to the central nervous system to be converted to the sensation of pain. Substance P and other sensory neuropeptides can be released from the peripheral terminals of sensory nerve fibers in the skin, muscle and joints. It is proposed that this release is involved in neurogenic inflammation, which is a local inflammatory response to certain types of infection or injury.[10]

While guided imagery administered preoperatively has been shown to reduce preoperative stress and the degree of postoperative pain, the mechanism of this effect has not been elucidated. Demonstrating a reduction in the absolute quantity or a change in the relative ratio of certain proinflammatory cytokines or Substance P in the perioperative setting and correlation with the degree of preoperative anxiety and postoperative pain would help define the value of perioperative bio-behavioral interventions.

Effect of problems or obstacles on the results

The inability to consistently following the biobehavioral intervention protocol could have increased participant anxiety and subsequently altered measured biomarker levels. Participant anxiety could have also increased in treatment group participants if participants were not comfortable with the auditory intervention provided or the media device/headphones. Delays in starting schedule surgical procedures could increase anxiety levels in both study groups which could lead to elevated biomarkers and/or postoperative pain.

Limitations

Compliance with the protocol was a serious limitation. Subjects were frequently not able to listen to the guided imagery intervention for the full 30-minute scheduled time period due to interruptions from medical staff performing preoperative tasks. Several subjects expressed a preference for an auditory intervention containing relaxing music. Others participants reported the earpieces were uncomfortable or difficulty operating the media player. One subject withdrew from the study because she did not want to listen to the section covering the details of her surgery (i.e., IV placement). Surgical procedures were not started as scheduled at times were due to unexpected surgical delays, prolonged room turn over times and ultimately longer preoperative holding times.

The study did not account for variations in preoperative diagnosis acuity. A patient with a greater acuity could report higher baseline anxiety and/or pain based on the preoperative diagnosis pathophysiology. Study findings might be difficult to apply to a male population since this study's participants were all females undergoing gynecologic procedures. This limitation could be compensated for by repeating the study with participants undergoing the same type of laparoscopic surgery and the study population equally distributed between genders.

Conclusion

Guided imagery has been shown in previous studies to play a role in decreasing anxiety and pain. Our study hypothesized that with the use of guided imagery there would be a direct correlation between the use of guided imagery and the reduction of proinflammatory cytokines and Substance P and reduced anxiety and pain. Our intent was to further exam the perioperative production of proinflammatory cytokines IL6 and IL8 and Substance P in the presence or absence of guided imagery. With the knowledge of IL6 and IL8 being proinflammatory mediators and encouraging heightened pain, we expected that our guided imagery would cause a reduction in these plasma levels as well as Substance P. There were no significant changes in IL8 and a modest increase in IL6 in both the control group and the treatment group. Substance P results did not demonstrate any statistically significant differences between groups. In the treatment group, an unexpected increase in IL6 presented with a p value of 0.02. Pain and anxiety were also measured. Our hypothesis suggested that patients receiving the guided

imagery would have a decrease in both of pain and anxiety. Collected data related to VAS and APAIS scales demonstrated an absence of significant difference in either the VAS or APAIS scales for the control group or the treatment group. Exposure to guided imagery was associated with a more rapid rise in IL6 levels during the progression of anesthesia and had no effect on the plasma levels of IL8 or Substance P or the VAS or APAIS scores over time.

Significance of Study or Project Results to Military Nursing

Pain can directly impact operational readiness and wartime functionality. Guided imagery is a bio-behavioral intervention designed to decrease pain, stress, and anxiety. Several investigations have documented use of guided imagery and associated improvement of postoperative outcomes. Many anesthesia providers have utilized forms of guided imagery and anecdotally reported both intraoperative and postoperative benefits, such as decreased reported levels of anxiety and pain. This investigation provides outcome data on a clinically relevant intervention military nurses can facilitate in a wide range of clinical settings. This intervention provides a method to decrease the need for pain medication, decrease hospital stays and facilitate an earlier return of active duty service members to work. This investigation directly addresses two priorities of the Tri-service Nursing research program Military Deployment, and Translating Knowledge & Research Findings into Practice in a Military Context.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

None to date

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Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Poster Presentations	"The Effect of a Bio-Behavioral Intervention on the Release of Cytokines"	AANA 78th Annual Conference Boston, MA 6 – 8 August 2011 PAO clearance approved 29 June 2011 AMSUS 117th Annual Conference Karen A. Reider Research Federal Nursing 23rd Annual Conference San Antonio, TX 8 November 2011 PAO clearance pending Sponsoring agencies Tri-Service Nursing Research Program & The Uniformed Services University
Podium Presentation	"The Effect of a Bio-Behavioral Intervention on the Release of Cytokines"	Sigma Theta Tau International Biennial Convention Grapevine, TX 30 October 2011

Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	None
Issued a Patent	None
Developed a cell line	None
Developed a tissue or serum repository	None
Developed a data registry	None

Recruitment and Retention Table

I. Recruitment and Retention Table

Subject Log - NNMC

Count	Group	Completed Study	Data Complete	Withdrew From Study
1	Treatment	Y	Y	N
2	Treatment	Y	Y	N
3	Treatment	Y	Y	N
4	Treatment	Y	Y	N
5	Control	Y	Y	N
6	Control	Y	Y	N
7	Treatment	Y	Y	N
8	Control	Y	Y	N
9	Treatment	Y	Y	N
10	Control	Y	Y	N
11	Treatment	Y	Y	N
12	Treatment	Y	Y	N
13	Control	Y	Y	N
14	Control	Y	Y	N
15	Control	Y	Y	N
16	Control	Y	Y	N
17	Treatment	Y	Y	N
18	Control	Y	Y	N
19	Treatment	Y	Y	N
20	Control	Y	Y	N
21	Control	Y	Y	N

Subject Log - WRAMC

Count	Group	Completed Study	Data Complete	Withdrew From Study		Count	Group	Completed Study	Withdrew from Study
1	Treatment	Y	Y	N		*25*	Control	Y	N
2	Control	Y	Y	N		*26*	Control	Y	N
3	Treatment	Y	Y	N		*27*	Treatment	Y	N
4	Control	Y	Y	N		*28*	Treatment	Y	N
5	Treatment	Y	Y	N		*29*	Control	Y	N
6	Treatment	Y	Y	N		*30*	Treatment	Y	N
7	Control	Y	Y	N		*31*	Treatment	Y	N
8	Control	Y	Y	N		*32*	Control	Y	N
9	Control	Y	Y	N		*33*	Control	Y	N
10	Control	**N**	**N**	N		*34*	Treatment	Y	N
11	Control	Y	Y	N		*35*	Control	Y	N
12	Treatment	Y	Y	N		*36*	Treatment	N/A	**Y**
13	Control	Y	Y	N		*37*	Treatment	Y	N
14	Treatment	Y	Y	N		*38*	Treatment	Y	N
15	Control	Y	Y	N		*39*	Treatment	Y	N
16	Treatment	Y	Y	N		*40*	Control	Y	N
17	Control	Y	Y	N		*41*	Control	Y	N
18	Treatment	Y	Y	N		*42*	Control	Y	N
19	Treatment	Y	Y	N		*43*	Control	Y	N
20	Control	Y	Y	N		*44*	Treatment	Y	N
21	Treatment	Y	Y	N		*45*	Treatment	Y	N
22	Control	Y	Y	N		*46*	Treatment	Y	N
23	Control	Y	Y	N		*47*	Treatment	Y	N
24	Treatment	Y	Y	N					

Summary regarding recruitment and retention

Sixty-eight subjects were recruited between 19 January 2011 and 8 June 2011. Recruitment took less time than budgeted. The majority of subjects were recruited from Walter Reed Army Medical Center (47) and the remaining were recruited from The National Naval Medical Center (21).

Sixty-seven subjects remained enrolled in the study. One subject withdrew from the study. That participant stated she did not want to listen to the information provided by the guided imagery describing the details of her procedure. One subject was unable to be reached by telephone to obtain assessment of her pain. However, she did not disenroll. We were successful in obtaining assessments of pain for sixty-six subjects in the study.

MILITARY BRANCH BREAKDOWN

Data was not collected pertaining to military branch of participants. However, data was collected identifying if the participant was an active duty military service member or a spouse or child of an active duty service member:

20	Active Duty	23 subjects
30	First Spouse	39 subjects
31-39	Subsequent Spouses	6 subjects
01	First Child	
02	Second Child	
03	Third Child (up to 09)	

Demographic Characteristics of the Sample

Characteristics	
Age (yrs)	38.9 ± 9.6
Women, n (%)	68 (100%)
Race	
White, n (%)	36 (52.9%)
Black, n (%)	21 (30.8%)
Hispanic or Latino, n (%)	6 (8.8%)
Other, n (%)	3 (4.4%)

Note: Missing data for 2 subjects

Service Component (*in lieu of Military Service/Civilian*)

20	Active Duty	23 subjects
30	First Spouse	39 subjects
31-39	Subsequent Spouses	6 subjects
01	First Child	
02	Second Child	
03	Third Child (up to 09)	

Type of Gynelogical Procedure			
0	Diagnostic Laparoscopy	17	(25.0 %)
1	Laparoscopic Abdominal Hysterectomy	15	(22.1 %)
2	Laparoscopic-Assisted Vaginal Hysterectomy	5	(7.4 %)
3	Laparoscopic Tubal Ligation/Anastamosis	4	(5.9 %)
4	Laparoscopic Salping Oophorectomy	15	(22.1 %)
5	Laparoscopic Cystectomy	4	(5.9 %)
6	Davinci	7	(10.3 %)

Note: Missing data for 1 subject

Final Budget Report

See attached

HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

Award#/Name : 63010 - THE EFFECT OF A BIO-BEHAVIORAL INTERVENTION
Project#/Name: 304025 - TSN RELEASE OF CYTOKINES
Task#/Name : 1.00 - ORIGINAL
Task Manager : BURGE, DONNA
Task Period : 9/1/2009 to 12/30/2011
Task Description: G161KQ
Performance Location :
Department :
Task Budgetary Control : Absolute

Task Budget Summary Report

Current As of : December 19, 2011

	Budgetary Control	Budget	Open Commitments	Task-to-Date Expenses	Total Funds Used	Balance Available	Percent Available
PERSONNEL	Absolute	45,459.00	.00	38,182.97	38,182.97	7,276.03	16.0
SUPPLIES	Advisory	28,488.00	1,388.90	26,904.74	28,293.64	194.36	.7
DOMESTIC TRAVEL	Absolute	5,400.00	1,844.62	2,166.52	4,011.14	1,388.86	25.7
OTHER DIRECT COSTS	Advisory	27,175.00	33,844.00	545.00	34,389.00	-7,214.00	-26.5
SUBAWARDS	Absolute	17,380.00	.00	.00	.00	17,380.00	100.0
TOTAL DIRECT COSTS		**123,902.00**	**37,077.52**	**67,799.23**	**104,876.75**	**19,025.25**	**15.4**
F & A (NON-CAS)	Absolute	58,315.00	.00	1,594.35	1,594.35	56,720.65	97.3
ON-SITE OVERHEAD	Advisory	.00	12,267.48	20,428.01	32,695.49	-32,695.49	.0
COMPANY-WIDE G & A	Advisory	.00	6,156.56	10,888.50	17,045.06	-17,045.06	.0
TOTAL INDIRECT COSTS		**58,315.00**	**18,424.04**	**32,910.86**	**51,334.90**	**6,980.10**	**12.0**
TOTAL TASK COSTS		**182,217.00**	**55,501.56**	**100,710.09**	**156,211.65**	**26,005.35**	**14.3**

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